

In the Claims:

Please cancel claims 2, 6 and 24 without prejudice or disclaimer of the subject matter contained therein, amend the claims to read as follows and enter new claims 37-39 (see enclosed version with markings to show changes made):

D¹ 1. (Four Times Amended) A delivery device for treatment of erectile dysfunction in a patient, consisting of a rigid disk, wherein the rigid disk is made of a mixture of materials, wherein the mixture of materials consists essentially of a filmogenic polymer and an effective dose of a therapeutic agent suitable for treating erectile dysfunction.

3. (Once Amended) The delivery device according to claim 1, wherein the therapeutic agent is a prostaglandin.

D² 4. (Once Amended) The delivery device according to claim 3, wherein the prostaglandin is prostaglandin E1.

5. (Once Amended) The delivery device according to claim 1, wherein the therapeutic agent is selected from the group consisting of: a vasodilator, a smooth muscle relaxant, an anti-depressant, a parasympathetic stimulator, a renin-angiotensin system inhibitor, a local anesthetic, an α -blocker, and a calcium channel blocker.

D³ 7. (Thrice Amended) The delivery device according to claim 38, wherein the additional therapeutic agent is selected from the group consisting of: prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a papaverine, a nitroglycerin, a phentolamine, a moxislyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

8. (Thrice Amended) The delivery device according to claim 37, wherein the enhancer is at least one selected from the group consisting of a glycolipid, a non-esterified fatty

acid, an aliphatic alcohol, a fatty acid ester of an aliphatic alcohol, a cyclohexanol, a fatty acid ester of glycerol, a glycol, an aliphatic alcohol ether of a glycol, and a surfactant.

9. (Twice Amended) The delivery device according to claim 8, wherein the filmogenic polymer is polyvinyl pyrrolidone, the therapeutic agent is prostaglandin E1, the enhancer is hexyldecyl stearate, and the plasticizer is PEG 400.

10. (Thrice Amended) The delivery device according to claim ³⁹37, wherein the filmogenic material is present in an amount of 5 to 100%, the therapeutic agent is present in an amount of 0.1 to 20% w/w, the enhancer is present in an amount of 0.01 to 15%, and the plasticizer is present in an amount of 1 to 70%, each on a weight basis.

Tm 11. (Twice Amended) The delivery device according to claim 9, having polyvinyl pyrrolidone present in an amount that is 40 to 45%, having prostaglandin E1 present in an amount that is 5 to 10%, having Eutanol G16S present in an amount that is 1 to 4%, and having PEG 400 present in an amount that is 40 to 50%.

12. (Twice Amended) The delivery device according to claim 9, having polyvinyl pyrrolidone present in an amount that is 40 to 45%, having prostaglandin E1 present in an amount that is 5 to 10%, having hexyldecyl stearate present in an amount that is 1 to 4%, and having PEG 400 present in an amount that is 40 to 50%.

13. (Once Amended) The delivery device according to claim 1, wherein the filmogenic polymer is selected from the group consisting of a synthetic polymer, a semi-synthetic polymer, and a naturally occurring polymer.

14. (Once Amended) The delivery device according to claim 13, wherein the synthetic polymer is polyvinyl pyrrolidone.

15. (Once Amended) The delivery device according to claim 13, wherein the naturally occurring polymer is from a plant.
16. (Once Amended) The delivery device according to claim 15, wherein the plant polymer is a gliadin.
17. (Thrice Amended) The delivery device according to claim ³⁹~~37~~, having a plasticizer in an amount less than 30% on a dry weight basis.
18. (Once Amended) The delivery device according to claim 1, wherein delivery is transdermal.
19. (Once Amended) The delivery device according to claim 1, wherein delivery is transmucosal.
20. (Once Amended) The delivery device according to claim 1, wherein the effective dose is released into the subject within one hour.
21. (Four Times Amended) A method of treating erectile dysfunction, comprising:
selecting a device consisting of a rigid disk, wherein the rigid disk is made of a mixture of materials, wherein the mixture of materials consists essentially of a filmogenic polymer and an effective dose of at least one therapeutic agent suitable for treating erectile dysfunction;
wetting a penile surface; and
placing the device in contact with the wetted penile surface delivering the at least one therapeutic agent to the penile surface over an effective period of time.
22. (Twice Amended) The method according to claim 21, wherein the therapeutic agent is selected from the group consisting of a prostaglandin, a testosterone, a yohimbine, a pentoxifylline, a trazodone, an apomorphine, a sildenafil, a minoxidil, a misoprostol, a

papaverine, a nitroglycerin, a phentolamine, a moxislyte, a linsidomine, a linear peptide, a cyclic peptide, and a pyridylguanidine compound.

23. (Once Amended) The method according to claim 21, wherein the therapeutic agent is present in a range of 0.1-15%, on a dry weight basis.

26. (Twice Amended) The method according to claim ⁴¹39, wherein the plasticizer is present in an amount that is less than 30% on a dry weight basis.

27. (Twice Amended) The method according to claim ⁴¹39, wherein the plasticizer is a polyethylene glycol (PEG).

28. (Once Amended) The method according to claim 27, wherein the PEG is PEG 400.

29. (Once Amended) The method according to claim 21, wherein the filmogenic polymer is a synthetic polymer.

30. (Once Amended) The method according to claim 29, wherein the synthetic polymer is polyvinyl pyrrolidone.

31. (Once Amended) The method according to claim 21, wherein the filmogenic polymer is a plant protein.

32. (Once Amended) The method according to claim 23, wherein the plant protein is a prolamine.

33. (Once Amended) The method according to claim 32, wherein the prolamine is a gliadin.

34. (Once Amended) The method according to claim 21, wherein the effective period of time is 5-100 minutes.

35. (Once Amended) The method according to claim 34, wherein the effective period of time is 30-60 minutes.

36. (Once Amended) The method according to claim 21, wherein the penile surface is selected from the group consisting of the shaft and the glans.

Rule 2.126 37. 37 A delivery device for treatment of erectile dysfunction in a patient, consisting of a rigid disk, wherein the rigid disk is made of a mixture of materials, wherein the mixture of materials consists essentially of a filmogenic polymer, an effective dose of a therapeutic agent suitable for treating erectile dysfunction, and at least one additive selected from the group consisting of a stabilizer, a solubilizer, an enhancer and a plasticizer.

Rule 1.126 40 38. A delivery device for treatment of erectile dysfunction in a patient, consisting of a rigid disk, wherein the rigid disk is made of a mixture of materials, wherein the mixture of materials consists essentially of a filmogenic polymer, an effective dose of a therapeutic agent suitable for treating erectile dysfunction, and at least one additional therapeutic agent.

Rule 1.126 41 39. A method of treating erectile dysfunction, comprising:
selecting a device consisting of a rigid disk, wherein the rigid disk is made of a mixture of materials, wherein the mixture of materials consists essentially of a filmogenic polymer, an effective dose of at least one therapeutic agent suitable for treating erectile dysfunction and a plasticizer;
wetting a penile surface; and
placing the device in contact with the wetted penile surface delivering the at least one therapeutic agent to the penile surface over an effective period of time.